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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,521	12/10/2001	Martin Schulein	4366.220-US	2575
25908	7590	11/25/2003	EXAMINER	
NOVOZYMES NORTH AMERICA, INC.			SLOBODYANSKY, ELIZABETH	
500 FIFTH AVENUE			ART UNIT	
SUITE 1600			PAPER NUMBER	
NEW YORK, NY 10110			1652	

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,521

Applicant(s)

SCHULEIN ET AL.

Examiner

Elizabeth Slobodyansky

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 132-160 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 132-160 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1652

DETAILED ACTION

The amendment filed September 11, 2003 amending the specification to insert the reference to the prior applications and correct clerical errors, canceling claims 106-131 and adding claims 132-160 has been entered.

The statement regarding the biological Deposit *Saccharomyces cerevisiae* DSM 10081 is given on page 8 of Remarks.

Claims 132-160 are pending.

Priority

Applicants can not obtain the benefit of the priority date of Danish application 0272/95 filed March 17, 1995 because they have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: the specification should be amended to indicate that grandparent application 08/651,136 is a continuation of PCT/DK96/00105 filed March 18, 1996.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. 37 CFR 1.821(d) requires the use of assigned sequence

Art Unit: 1652

identifier in all instances where the description or claims of a patent application discuss sequences.

The following are examples of incompliance where the sequence containing more than ten nucleotides is given without a sequence identifier: the sequences shown in Figures 1 and 3 are not identified by the sequence identifiers either in the drawings or in the Brief Description of the Drawings.

There is no paper copy of the Sequence listing in the case. The computer readable form has been transferred from the parent case. Applicants are required to *provide the paper copy identical to the computer readable form and the statement attesting that the content of the paper and the computer readable copies of the "Sequence Listing" are identical as required by 37 CFR 1.821(f).*

Applicants are requested to indicate pages of the specification, as originally filed, containing the Sequence Listing.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 89, line 7, for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Art Unit: 1652

The disclosure is objected to because some abbreviations are not defined such as, for example, "S-CEVU" (e.g., page 57, 66), "DSC" (e.g., page 66).

It is suggested that the first time an abbreviation is used, that the abbreviated term be written out in full, followed by its abbreviation in parenthesis.

Amending the specification on page 67, line 1, to "Differential scanning calometry (DSC)" is suggested.

On pages 68, 70, 71, etc. there are no headings to the table columns. Hence it is unclear what numbers 250, 1000 and 50, 200 mean in these columns.

The amendment filed September 11, 2003 attempts to incorporate the prior applications by reference. Such is improper because an incorporation by reference statement must be included in the specification as-filed and cannot be added after its filing date see (MPEP 201.06(c)).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1652

Claims 132-160 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a detergent composition comprising the endoglucanase of SEQ ID NO:12, does not reasonably provide enablement for a detergent composition comprising an endoglucanase with an amino acid sequence 80%, or 90% homologous to SEQ ID NO:12 or encoded by a DNA that hybridizes to SEQ ID NO:11 under hybridization conditions comprising a wash step at 60° C, 65° C, 70° C or 75° C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of endoglucanases broadly encompassed by the claims. Since the amino acid sequence of a protein determines

Art Unit: 1652

its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of endoglucanase of SEQ ID NO:12 from *Thielavia terrestris* NRRL 8126 (page 16, lines 31-33).

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. Producing variants as claimed by applicants requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the great number of variants retain the claimed activity.

The specification does not support the broad scope of the claims which encompass variant endoglucanases with homology to SEQ ID NO:12 of at least 80% or

Art Unit: 1652

90% because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting endoglucanase activity; (B) the general tolerance of endoglucanase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any endoglucanase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have **not** provided sufficient guidance to enable one of ordinary skill in the art to make the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a great number of modifications in SEQ ID NO:12.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without necessary guidance, beyond that provided, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

Art Unit: 1652

patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 132-160 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Skinner et al in view of Saito et al.

Claim 132-160 are included in this 103 rejection to the extent that they encompass a detergent composition comprising the endoglucanase of SEQ ID NO:12 which is enabled. Thus both the 112, 1st paragraph, scope of enablement and 103 rejections are proper.

Skinner et al. (US Patent 4,081,328, form PTO-892 mailed March 10, 2003) teach the production of a cellulase by a thermophilic fungus *Thielavia terrestris* NRRL 8126, the strain that is the source of the endoglucanase of the instant invention. They teach that said cellulase exhibits both C₁ and C_x enzyme activity at temperatures from 60° C to about 70° C at pH from about 5.0 to about 5.6 (column 3, lines 54-64; column 6, lines 23-33, claim 1). C_x activity is measured using as a substrate carboxymethylcellulose (CMC) (column 1, lines 38-41). This is the same activity as measured by Applicants as S-CEVU (page 57).

Since the amino acid sequence is an inherent property of a protein, the isolated cellulase taught by Skinner et al. appears to be identical to the endoglucanase of the instant invention.

Art Unit: 1652

Saito et al. (US Patent 5,314,637) teach detergent compositions comprising cellulase, surfactant and builder and its use in laundry (claim 1 and columns 10-11, Example 4).

It would have been obvious to one of ordinary skill in the art the invention was made to prepare a detergent composition comprising the endoglucanase taught by Skinner et al. and use it in laundry. One of ordinary skill in the art would have been motivated to use endoglucanase taught by Skinner et al. because of its higher thermostability.

Response to Arguments

Applicant's arguments filed September 11, 2003 have been fully considered but they are not persuasive.

Regarding the reference to the prior applications "Applicants note that this application does not claim the benefit of PCT/DK96/00105 filed March 18, 1996" (Remarks, page 7). The examiner points out that Applicants claim the benefit of 08/651,136 issued as US Patent 6,001,639 which is a continuation of PCT/DK96/00105 filed March 18, 1996 which claims the priority date of Danish application 0272/95 filed March 17, 1995. Applicants cannot change the continuation data of the prior application, now a patent, at this time.

Art Unit: 1652

With regard to the Sequence Listing, Applicants are requested to indicate the pages of the specification as filed containing the Sequence Listing.

Applicants argue that "The abbreviation "S-CEVU" is defined on page 57" (page 7). Careful reading of said page did not reveal the definition.

With regard to the tables, "Applicants submit that the results disclosed in the tables on pages 68 and 79 can be understood by persons of ordinary skill in the art without any headings" (page 7). This is not agreed with and Applicants are required to indicate what the numbers show.

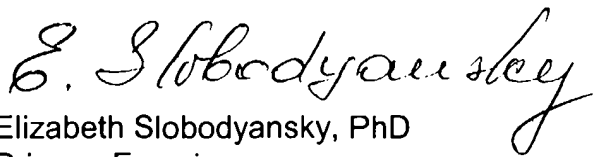
With regard to the 103 rejection, Applicants argue that "Neither Skinner et al. nor Yu et al. teach or suggest detergent compositions. Moreover, the instant specification demonstrates that the cellulases of the present invention have improved performance in detergents. See, e.g., pages 68-72 of the specification. These results are surprising and unexpected" (page 9). This is not persuasive because if the performance of the detergent composition comprising the claimed polypeptide of the invention is due to the claimed polypeptide, it is inherent in that polypeptide. If the performance of the detergent composition comprising the claimed polypeptide is due to a specific detergent, said detergent must be disclosed as an essential for imparting the surprising and unexpected results.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script that reads "E. Slobodyansky". The signature is written in black ink and is positioned above the printed name and title.

Elizabeth Slobodyansky, PhD
Primary Examiner

November 21, 2003